

Epidemiology and the planned new Data Protection Directive of the European Union: a symposium report

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The European Union Directive revision

Currently personal data protection, including health related data, in the European Union (EU) is regulated by the 'European Parliament and Council Directive 95/46/EC of October 24, 1995'. Within the EU 'directives' are addressed to the twenty-seven member states and are not automatically binding to citizens: the member states must transpose the directive in internal law, which allows – depending on the formulation – a leeway as to the exact specification of the rules to be adopted and executed.

The adequacy of the directive to satisfy present day societal needs of data protection has been called into question on the more than fifteen years of experience with national applications and the huge intervening developments in the information technology (IT) area (web, social networks etc..). These issues were reviewed by a Rand Europe expert group, sponsored by the EU Information Commissioner's Office, [1] that cites six main changes to be confronted in a much needed revision of the directive:

- (1) a clearer definition of personal privacy as distinct from personal data protection;
- (2) risk assessment: estimating the actual risk(s) for citizens providing personal data;
- (3) rights of individuals versus benefits to society;
- (4) 'transparency': people knowing or not knowing where personal data are stored and where they can be transferred;
- (5) Exercise of informed, free choice when releasing one's personal data;
- (6) Accountability: who is held responsible for the custody of the data and which authority can be approached to redress actual or presumed torts.

EU Justice Commissioner Viviane Reding has declared the revision of the directive a high priority, to be adopted within 2014 at the EU level. Two points appear particularly relevant at the time of writing this report (fall 2011). First it is not yet established whether the revision will maintain the form of a directive or will be changed into a 'regulation'. Unlike a directive, a EU regulation shall have general application. It shall be binding in its entirety and directly applicable in all members states': the implication is that margins of flexibility for application in a given country would disappear. Second, the principles of the revision have been extensively presented [2] but no draft text of the directive (or regulation) is available, though it should be by the end of 2011. Clearly the 'devil is in the detail' and, for example, the possibility of exempting some epidemiological uses of personal data from informed consent entirely depends on the actual phrasing of the relevant passages of the directive text.

Epidemiology and the European Union Directive

Personal data should be here understood as data that carry information that, directly or indirectly, allow to identify the person to which they refer to. The directive covers, and will continue to cover, the citizens' protection as to personal data storage, transfer and use for a wide range of purposes, administrative (in public and private business), police and judicial, marketing and other commercial purposes, web exchanges, social

networks, health services etc. Scientific research, including demographic and epidemiological research, and public health appear only as a quantitatively lesser component within this complex. This entails the risk that their specific functional needs may not be given adequate attention in the new directive which should in particular consider:

Audit studies. An important distinction should be made between use of such data for monitoring and auditing the health services performance and 'ad hoc' epidemiological research. There is undoubtedly an ethical obligation to ensure that medical services work to the actual advantage of people: hence the use of personal data, typically medical records, for auditing interventions of all kind may not in general require informed consent, provided the data handling –including, for instance, appropriate encrypting procedures to preserve confidentiality – are under the regular control of an independent surveillance body.

Disease registries. In many countries registries have been established, e.g. on cancer, myocardial infarction, birth defects, by governmental authorities or are officially recognized by them, involving mandatory rather than voluntary, consent-dependent, collection of data, e.g. the automatic transfer and long-term storage of key data on each case of cancer to the population cancer Registry. This obligation is supported by the scientific and public health importance of having a comprehensive and prolonged information on the totality of the population (all ages, genders, social classes etc.) as well as by the related ethical principle that burdens and benefits should be distributed equitably across all population groups.

Studies using registry data. Epidemiological studies using data from such registries, as well as studies that link data from several registries (including birth and death registries) or from registries and other publicly available sources, involve the use of data that have been collected without the need of informed consent of the individuals involved. Hence no consent should be in general required for such studies provided an ethical review committee has approved the study protocol. Persons need not be aware that they are enlisted in a compulsory registry: hence special care, including for instance contact via the persons' physicians, is necessary should investigators approach them to obtain additional information. In this context it is relevant that abuse is much more likely if data linking and sharing is allowed between health-related databases and other databases (e.g. commercial, police, fiscal) than when data are shared between health-related databases.

Public health emergencies. In the investigation of public health emergencies, like disease outbreaks of unknown origin or environmental disasters, it may be materially impossible to obtain informed consent to the use of personal data, and a timely ethical review of the investigation protocol may also be unfeasible. The best policy for these situations is for the public health authorities to predispose the basic research designs for various types of emergencies and have their ethical implications (including consent and data protection requirements) examined prior to any actual occurrence of an emergency.

Problematic ethical issues

While a large in principle consensus has matured in the societies of the EU on the issues just mentioned (and should be reflected in the directive) ethical positions on other issues appear still more on the move. One prominent case is the use of biological specimens collected for storage and future analyses, including genetic tests, that cannot be specified in advance. No truly informed consent to the use by the subject donating the specimen is possible in these circumstances: yet to assume that the very fact of the donation implies consent to *any* use (including for instance development of commercial products) is highly questionable. Some compromise should be sought between an

impossible consent to each specific analysis and the right of the person to put limits to the uses of the information generated by testing the specimens in a future that may last several decades.

Opportunities for action

Epidemiological research is essential to the maintenance and improvement of population health and consequently it is also essential that the revision of the EU directive takes explicitly into account the specific requirements of epidemiological research. Three suggestions to 'make a case for epidemiology' can be put forward:

- (1) to join forces of the International Epidemiological Association, national societies of epidemiology, European Public Health Association (EUPHA) and other societies (in the field of statistics, demography, sociology) to reach and present a common position in respect to the directive revision. Some work of clarification may be required as, for example, one recent document from the 5th Nordic Meeting of Epidemiology [3] argued for a directive allowing latitude of application within each country, while a document [4] from an EUPHA group discussion proposes 'a unified framework through which public health monitoring can be properly conducted' in all EU countries'.
- (2) to channel the epidemiologists' standpoint through high profile, powerful scientific and professional organizations like the UK Royal Statistical Society and Royal College of Physicians.
- (3) to promote people's support for instance by asking, if possible in the frame of formal exercises, what decision would they take in respect to informed consent, personal data protection etc. when faced with different realistic scenarios ('vignettes') of epidemiological studies relevant to health improvement.

[1] Robinson N, Graux H, Botterman M, Valeri L. *Review of the European Data Protection Directive*. Cambridge : Rand Europe 2009.

[2] European Commission. A comprehensive approach on personal data protection in the European Union . COM (2010) 609 final . Brussels : European Commission,4/11/2010.

[3] Stenbeck M, Gissler M, Haraldsdottir S, Heimisdottir M, Kesmodel US, Melbye M *et al*. The planned changes of the European Data Protection Directive may pose a threat to important health research. Personal communication, August 2011.

[4] Carinci F, Di Iorio CT, Ricciardi W, Klazinga N, Verschuuren M. Revision of the European Data Protection Directive : opportunity or threat for public health monitoring ? *Eur J Public Health* 2011; doi : 10.1093/eurpub/ckr100